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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,842	11/14/2001	James Hunter Boone	TLAB.79219	3654

7590 11/18/2003

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/18/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,842	BOONE ET AL	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I (claims 1-9 and 12-16) drawn to methods of distinguishing/differentiating irritable bowel syndrome in Paper No. 8 filed 8/4/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 10-11 and 17-20 have been canceled without prejudice or disclaimer at Applicants request. Currently claims 1-9 and 12-16 are pending and under consideration.

Drawings

3. No drawings were filed in the instant application.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

5. The information disclosure statement filed 4/26/03 in paper #6 has been considered as to the merits before First Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-9 and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1 and 12 are vague and indefinite because it is not clear how the methods will distinguish irritable bowel syndrome from inflammatory bowel disease. As recited claim 1 merely precludes irritable bowel syndrome but does not speak to the actual determination of inflammatory bowel syndrome. Claim 12 merely recites the detection of elevated endogenous lactoferrin but does not correlate the elevation to bowel syndrome. The claims do not set forth clear, distinct and positive process steps with a resolution or correlation step that clearly relates to the preamble. Appropriate correction is required.

B. Claims 1 and 12 are vague and indefinite because it is not clear as to what interaction the sample and the antibodies to human lactoferrin will produce. As recited the claims merely require a contact of the two reagents. This does not give way to subsequent correlation of binding components and correlation to bowel syndrome. The claim should include clear interaction of the sample and antibodies followed by clear correlation with respect to the disease detection. Appropriate correction is required.

C. Claims 4 and 16 are indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of" with the use of the conjugate "or" in listing species. See MPEP 706.03(Y).

D. The terms "treated sample" and "readable sample" in claims 6-9 and 12-14 are relative terms, which renders the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear that applicant intends to mean bound sample or simply contacted sample will meet the limitation with respect to treated and readable. The claim should read wherein the antibody bound sample is treated sample and enzyme-linked antibody bound sample is the readable sample for clarity. Please correct .

E. Claims 7 and 12 are vague and indefinite because it is not clear as to what the term "enzyme-linked polyclonal antibody" encompasses. Is it Applicants intent to mean the polyclonal antibody is bound to a detectable enzyme or is the term directed to polyclonal antibodies that can be employed and detected in an enzyme-linked immunoassay? Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-2 and 4-7 are rejected under 35 U.S.C.103(a) as being unpatentable over Guerrant et al. (US Patent #5,124,252) in view of Peen et al. (Gut, 1996, 38, 135-140) and in further view of Sugi et al. (The American Journal of Gastroenterology, Vol.91, No.5, 927-934, 1996).

Guerrant et al. teach a method to measure lactoferrin in fecal samples. Specifically and antibody for lactoferein is employed to measure lactoferrin in inflammatory diarrheal specimens. See abstract. The method was performed in an enzyme-linked immunoassay format. Lactoferrin levels were demonstrated to increase in inflammatory specimens and not in controls. See column 4 lines 20-22. Guerrant et al. are silent with respect to the utility of polyclonal antibodies, However Peen et al. demonstrate polyclonal antibody detection of lactoferrin in their procedure.

Peen et al. teach the detection of lactoferrin in inflamed human intestine and liver. See Table on page 137. Lactoferrin was measured in biopsy specimens from patients with inflammatory bowel disease and primary sclerosing cholangitis. Polyclonal rabbit anti-human lactoferrin antibodies were used for immunohistochemistry and the antibody measurements were done by enzyme immunoassay. See abstract.

Guerrant et al. further differ from the instant invention in not specifically teaching lactoferrin detection particularly in inflammatory bowel disease.

Sugi et al. teach this limitation. Sugi et al. disclose that lactoferrin levels were elevated in fecal samples of patients with inflammatory bowel disease. See abstract.

It would have been obvious at the time of applicants' invention to measure lactoferrin in fecal samples of patients with inflammatory bowel disease as taught by Sugi et al. utilizing polyclonal antibodies to lactoferrin as demonstrated by Peen et al. in the method of Guerrant et al. because Sugi et al. taught that the extracellular (endogenous) release of lactoferrin (Lf) was most efficient and most stable in fecal samples. See abstract.

While the use of polyclonal antibodies is art recognized as shown in the reference of Peen et al. Absent evidence to the contrary the utility of polyclonal antibodies is mere optimization of the prior art assay wherein antibody reagents are routinely modified.

II. Claims 3, 8-9, and 12-16 are rejected under 35 U.S.C.103(a) as being unpatentable over Guerrant et al. (US Patent #5,124,252) in view of Peen et al. (Gut, 1996, 38, 135-140) and in further view of Sugi et al. (The American Journal of Gastroenterology, Vol.91, No.5, 927-934, 1996) and in further view of Peen et al. (Gut, 1993, 34, 56-62).

Guerrant et al. (US Patent #5,124,252) in view of Peen et al. (Gut, 1996, 38, 135-140) and in further view of Sugi et al. (The American Journal of Gastroenterology, Vol.91, No.5, 927-934, 1996) are set forth above.

Guerrant et al. (US Patent #5,124,252) in view of Peen et al. (Gut, 1996, 38, 135-140) and in further view of Sugi et al. (The American Journal of Gastroenterology, Vol.91, No.5, 927-934, 1996) differ from the instant invention in not specifically teaching the optical density measurements at 450nm, greater that .200, at a 1:400 dilution in their assay procedures.

However, Pene et al. teach ELISA procedures measuring lactloferrin with these parameters. See page 57 –58.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize measure lactoferrin at an optical density measurements at 450nm, greater that .200, at a 1:400 dilution as taught by Peen et al. in the method of Guerrant et al. (US Patent #5,124,252) in view of Peen et al. (Gut, 1996, 38, 135-140) and in further view of Sugi et al. (The American Journal of Gastroenterology, Vol.91, No.5, 927-934, 1996) because Peen et al. taught that their method was quick and accurate. See Figure 1.

8. For reasons aforementioned, no claims are allowed.

Remarks

9. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Pool et al. (Gut, 1993, 34, 46-50) teach ELISA techniques to measure autoantibodies involved in inflammatory bowel disease.

B. Guerrant et al. (US Patent #5,124,252) teach in vitro fecal tests to measure lactoferrin.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lisa V. Cook
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10/16/03

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10/16/03